NOV 1 9 2003

510(k) Summary

Submitter: IDev Technologies, Inc.
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K033188

Date Prepared: September 30, 2003

Trade Name: Texan™ Foreign Body Retrieval Device

Common Name: Snare

Classification Name: Device, Percutaneous Retrieval (21 CFR 870.5150)

Product Code: MMX

Predicate Device: ev3 Amplatz "Goose-Neck" Snare Device

Device Description:
The Texan™ is comprised of the following:

- A nitinol wire formed into a loop. The wire is secured distally to the catheter body; the proximal wire end is attached to a shaft that functions as a push-rod, and passes through a dedicated catheter lumen. The "loop" portion of the wire has a radiopaque feature, comprised of Nitinol wire with a platinum core and tungsten sheath
- A two-lumen catheter body. One lumen is dedicated for use by the loop wire, which is secured to the push-rod (shaft) at the proximal end of the loop wire. The second and larger lumen is dedicated for use of a guidewire and contrast. The proximal catheter end is to be attached to a hemostasis valve with a flush port.
  - The hemostasis valve has 2 ports:
    - side port having access to the guidewire-dedicated lumen for contrast injection; and
    - primary port dedicated for a guidewire, and having a Tuohy-Borst connector.

The loop is activated by pushing the shaft distal to the Touhy-Borst connector while holding the Touhy-Borst stationary. The device should be manipulated in such a way that the loop can surround the foreign body. To capture the foreign body, the user shall slowly tighten the loop around the foreign body by pulling the shaft proximally while the device is held stationary in position. Once the loop is tightened around the foreign body the shaft shall be lockeda by rotating the homeostasis valve connected to the proximal end of the shaft clockwise. Retrieval of the foreign body is performed by slowly withdrawing the Texan™ and the foreign body as a unit into the sheath.

Intended Use:
The Texan™ is intended for use as a tool to retrieve and manipulate foreign bodies from distal peripheral vessels of the cardiovascular system.

Technological Characteristics Compared to Predicate:
IDev Technologies, Inc. considers the Texan™ Foreign Body Retrieval Device as substantially equivalent to ev3's Amplatz "Goose-Neck" Snare as listed in the following:

- Indication for Use
- *Loop*
  - Material
  - Radiopacity
  - Orientation
  - Torque Control/Steerability
  - Guidewire Compatibility
  - Shaft Reinforcement
  - Configuration
  - Loop Size
  - Adjustability
  - Catheter
  - French Size
  - Contract Injectability
- *Function*
  - Advancement
  - Catheter Advancement
  - Loop Usage

Non-clinical Performance Testing:
The Texan™ Foreign Body Retrieval Device has successfully passed all functional and safety testing requirements to ensure substantial equivalence to the predicate device. The testing is described below:

- Accelerated Aging / Packaging - to determine effects of time & environment on device and packaging materials, to substantiate 1-year shelf life. Tests include package Seal Peel, Burst, Dye Penetration, and device functionality after aging.
- Packaging / Shipping Integrity - to determine possible adverse effects of shipping & transportation environments on survivability of device packaging and construction materials.
- Dimensional - to insure that the device met dimensional requirements, as defined in the product specification.
- Tensile - to verify design meets minimum tensile strength requirements at all joints, as defined in product specification.
- Biocompatibility - to determine the potential toxicity resulting from contact of the component materials of the device with the body.
- Animal Study - to evaluate the safety and efficacy of a proposed device, and evaluate operational characteristics of the device with respect to utilization of a predicate device.

Conclusion:
IDev Technologies, Inc. considers the Texan™ Foreign Body Retrieval Device to be substantially equivalent to the ev3 Amplatz "Goose-Neck" Snare Device based on design and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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IDev Technologies, Inc.
c/o Ms. Lynne Davies
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Houston, TX 77058

Re: K033188
Texan™ Foreign Body Retrieval Device, Model TX30
Regulation Number: 21 CFR 870.5150
Regulation Name: Percutaneous Retrieval Device
Regulatory Class: Class II (two)
Product Code: MMX
Dated: September 30, 2003
Received: October 1, 2003

Dear Ms. Davies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: IDev Technologies, Inc.

510(k) Number (if known): K033188

Device Name: Texan™ Foreign Body Retrieval Device

Indications for Use: The Texan™ Foreign Body Retrieval Device is indicated for use as a tool to retrieve and manipulate foreign bodies from distal peripheral vessels of the cardiovascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033188

Prescription Use X
(Per 21 CFR 801.109)